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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,418	04/26/2006	Shirou Sawa	2006_0177A	7556

513 7590 11/14/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,418	SAWA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-11* is/are pending in the application.

4a) Of the above claim(s) *5-7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/26/2008, 3/6/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The previous action is vacated and the current action is present in its place.

Status of Application

1. The response filed July 7, 2208 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 1 and 5-10 have been amended.

   b. Claim 2 and 4 has been cancelled.

2. Claims 1, 3, 5-11 are pending in the case.

3. Due to the amendment of the claims and the new grounds of rejection the organic amine was expanded to include ethylenediamine.

4. Claims 1, 3, 8, 10-11 are present for examination.

5. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

6. All grounds not addressed in the action are withdrawn or moot.

7. New grounds of rejection are set forth in the current office action.

Information Disclosure Statement

8. The information disclosure statement filed 2/26/2008, and 3/6/2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation of EP 0243408 and there is no supplemental search report submitted. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the

submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

New Grounds of Rejection

9. Due to the amendment of the claims the new grounds of rejection are applied and the organic amine was expanded to include ethylenediamine:

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1,3, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa et al (U.S. Pat. No. 4910225).

Ogawa teaches a method of treating inflammatory eye disease with an ophthalmic composition comprised of a benzoylphenylacetic acid or its salt or the hydrate, in one or more compound mixtures, buffers, and optionally with an isotonizing agent, a microbiocidal agent, a preservative, a chelating agent, and a thickening agent . The concentration of the active ingredient may range from about 0.001% to about 10%, preferably in the range of 0.01 to about 5%. Ogawa teaches the composition to be useful in treating inflammatory ophthalmic conditions such as uveitis and conjunctivitis.

The composition can be administered in the form of eye drops, ointments and any other known compositions for topical administration to the eye. The eye drops are to be administered one to several drops per dose in a frequency of once to four times a day according to the clinical condition. The dosage may be adjusted according to symptoms.

The specific drug utilized is sodium 3-(4-bromobenzoyl) 2-aminophenylacetate/monohydrate at 0.1% with sodium edentate (EDTA), an organic amine specifically an ethylenediamine (EDTA is also known as ethylenediaminetetraacetic acid). The recitation of bromfenac to be in the humor for at least 24 hours is a recitation of intended effect which does not have patentable weight as the components present in the composition (e.g. bromfenac, the organic amine) in claim 1. The limitations to be met are the administration of the composition and its components to the eye for treating inflammation (Abstract, Col. 1, lines 33-38, 60-68, Col. 2, lines 1-36, 45-68, Col. 3, lines 30-54, Col. 4, lines 20-68, Col.5, lines 1-15-23, Col.6, lines 20-48, 53-68, Col.7, lines 1-68, Col8, lines 1-20, 25-68, Col.9, Example 1-2, Col.10, Example 6-7).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (U.S. Pat. No. 4910225) as applied to claims 1,3,and 8 above, in view of Kato (U.S. Pat. 5945121).

The teachings of Ogawa are addressed above.

Owaga et al. does not expressly teach the incorporation of taurine (aminoethylsulfonic acid).

Kato et al. teaches that taurine is effective in the treatment of dry eye, and other inflammatory conditions. Kato teaches that taurine when delivered to the eye is effective in the range of 0.5 to 3.0% by weight for the treatment of dry eye. When in an amount less that 0.5%wt. the treating effect on dry eye is weak, and when there is more than 3%wt., irritation to the eye occurs due to hypertonia (Col. 1, lines 10-48).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate taurine, as suggested by Kato et al., and produce the instant invention. It would have been obvious to one of skill in the art to incorporate taurine to compositions affecting inflammatory conditions, because taurine is known to be effective in suppressing the release of histamine which is the cascade resulting in inflammation (see Endo et al., Mechanisms…) and has been previously used in ophthalmic solutions (see Huth, U.S. Pat. Pub. No. 2004/0120916 for a summary). It is also naturally found in the eye as an amino acid found typically in the retina.

One of ordinary skill in the art would have been motivated to do this as it is routine in the art to have combine of drugs for the same purpose to provide a more effective composition to treat the condition desired. Owaga teaches explicitly, the incorporation of other active agents (Col. 4, lines 16-20).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

14. Applicant's arguments filed 07/07/2008 have been fully considered but they are not persuasive. Applicant ‘s argument that the active ingredient in Owaga is bromfenac and the active ingredient in Kato is taurine and that the active ingredients are not the same is not persuasive as combining two active ingredients for the same purpose is obvious and both components are active in the composition. The argument that the method is for intraocular penetration of bromfenac is not commensurate in scope with the claims as the claims are to the method of treating inflammatory disease of the eye (anterior and posterior segments) comprising the administration of bromfenac. The argument to other organic amines such as trometamol is not commensurate in scope with the instant claims as claims to other organic amines including trometamol are

withdrawn. The argument for unexpected results with regards to the intraocular penetration is not persuasive as they are not commensurate in scope with the instant claims as it is to a composition comprising bromfenac, taurine, and trometamol (trometamol withdrawn based on election). The claims are to a method comprising the administration of a composition of bromfenac and aminoalkysulfonic acid where taurine was elected and now includes ethylenediamines. The recitation of the duration does not have patentable weight as when the method of administration of the claimed components in the composition are met, the subsequent effects are to yield the same results as it is intrinsic to the composition and the mode of administration.

Conclusion

15. Claims 1, 3, 8, 10-11 are rejected.

16. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612